IN THE DISTRICT COURT OF THE UNITED STATES
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION

CIVIL CASE NO. 3:06cv368

HEATHER MICHELLE HORNE, Administratrix of the Estate of Zachary Clifton Horne, Deceased,	)	
Plaintiff,	)	
vs.	)	**MEMORANDUM OF DECISION AND ORDER**
NOVARTIS PHARMACEUTICALS CORPORATION,	)	
Defendant.	)	

THIS MATTER is before the Court on the Defendant's Motion to Dismiss [Doc. 10] and the Plaintiff's Objections [Doc. 27] to the Memorandum and Recommendation [Doc. 26] of Magistrate Judge Carl Horn, III, filed on January 8, 2007.

Pursuant to 28 U.S.C. § 636(b) and the standing Orders of Designation of this Court, the Defendant's Motion to Dismiss [Doc. 10] was referred to the Magistrate Judge for disposition or for a recommendation of disposition, as may be appropriate. On January 8, 2007, the Magistrate

Judge entered a Memorandum and Recommendation [Doc. 26], recommending that the Defendant's Motion to Dismiss [Doc. 10] be granted. The Plaintiff filed timely Objections [Doc. 27] to the Magistrate Judge's Recommendation [Doc. 26] on January 18, 2007, and the Defendant filed a Response [Doc. 28] to those Objections on February 5, 2007.

For the reasons set forth below, the Plaintiff's Objections [Doc. 27] to the Magistrate Judge's Recommendation [Doc. 26] are **OVERRULED IN PART**, and the Magistrate Judge's Recommendation [Doc. 26] is **ADOPTED IN PART** to the extent that the Magistrate Judge has recommended the dismissal of the Plaintiff's failure to warn and inadequate labeling claims on the basis of conflict preemption. However, to the extent that the Magistrate Judge recommended dismissal of the Plaintiff's claims which are not premised on a failure to warn or inadequate labeling on the basis of conflict preemption, the Magistrate Judge's Recommendation [Doc. 26] is **REJECTED IN PART**. The Court has independently reviewed the Plaintiff's remaining claims and, for the reasons stated herein, concludes that the Defendant's Motion to Dismiss [Doc. 10] should be **GRANTED IN PART** with respect to the Plaintiff's claims of negligent

labeling, packaging, promotion, marketing, and advertising; her claim of failure to warn; her claim for wantonness; and her claim of fraud, misrepresentation and suppression. The Motion to Dismiss [Doc. 10] is **DENIED IN PART** with respect to the Plaintiff's negligence claim related to the design, manufacture, research and development, testing, processing, distribution, and sale of Lotensin HCT® and her claim of breach of implied warranty of merchantability.

I. FACTUAL BACKGROUND AND PROCEDURAL HISTORY

Taking the allegations as set forth in the Plaintiff's Complaint as true, the following are the relevant facts for the purpose of the present motion. The Plaintiff[1] is a long-time sufferer of hypertension. [Complaint, Doc. 1-3 at ¶ 7]. For years, her doctor treated her with Lotensin HCT®, which is manufactured by the Defendant. [Id. at ¶¶ 6,7]. Lotensin HCT® is a brand name used by the Defendant to market and distribute benazepril, which is an angiotensin-converting-enzyme inhibitor ("ACE inhibitor"). [Id. at ¶ 6]. The Plaintiff became pregnant in October 2003. [Id. at ¶ 7]. She continued to be prescribed and to use Lotensin HCT® until December 16, 2003,

[1]The Plaintiff in this action is Heather Michelle Horne, Administratrix of the Estate of Zachary Clifton Horne, deceased. For ease of reference in reciting the facts of this case, the Court will use the term "Plaintiff" to refer to Ms. Horne in her individual capacity as well.

when she was seven weeks and four days pregnant. [Id. at ¶ 8]. At that point, Plaintiff's doctor changed her prescription to Aldomet (methyldopa). [Id. at ¶ 9]. From that point forward, until she gave birth to her son Zachary on July 9, 2004, the Plaintiff took Aldomet to treat her hypertension. [Id.]. Zachary was born with several heart defects and unilateral kidney defects. [Id. at ¶ 11]. He died on July 28, 2004 at age nineteen days as a result of these heart and kidney defects. [Id. at ¶ 12].

The Plaintiff alleges that the Lotensin HCT® package insert "failed to give any warning to women of child bearing years or those in their first trimester of pregnancy to avoid using Lotensin HCT®," and that the Defendant "proactively stated that fetal injury does not appear to be associated with use of Lotensin HCT® during the first trimester of pregnancy." [Id. at ¶ 13].

The package insert in question is dated August 2003 and was specifically approved by the FDA for Lotensin HCT®. The package insert contains the following pregnancy categories and warnings and other information:

USE IN PREGNANCY
When used in pregnancy during the second and third trimesters, ACE inhibitors can cause injury and even death to the developing fetus. When pregnancy is detected, Lotensin HCT should be discontinued as soon as possible. See **WARNINGS, Fetal/Neonatal Morbidity and Mortality.**

WARNINGS

* * *

Fetal/Neonatal Morbidity and Mortality

ACE inhibitors can cause fetal and neonatal morbidity and death when administered to pregnant women. Several dozen cases have been reported in the world literature. When pregnancy is detected, Lotensin HCT should be discontinued as soon as possible.

The use of ACE inhibitors during the second and third trimesters of pregnancy has been associated with fetal and neonatal injury, including hypotension, neonatal skull hypoplasia, anuria, reversible or irreversible renal failure, and death. Oligohydramnios has been reported, presumably resulting from decreased fetal renal function; oligohydramnios in this setting has been associated with fetal limb contractures, craniofacial deformation, and hypoplastic lung development. Prematurity, intrauterine growth retardation, and patient ductus arteriosus have also been reported, although it is not clear whether these occurrences were due to the ACE-inhibitor exposure.

These adverse effects do not appear to have resulted from intrauterine ACE-inhibitor exposure that has been limited to the first trimester. Mothers whose embryos and fetuses are exposed to ACE inhibitors only during the first trimester should be so informed. Nonetheless, when patients become pregnant, physicians should make every effort to discontinue the use of benazepril as soon as possible.

Rarely (probably less often than once in every thousand pregnancies), no alternative to ACE inhibitors will be found. In these rare cases, the mothers should be apprised of the potential hazards to their fetuses, and serial ultrasound examinations should be performed to assess the intraamniotic environment.

* * *

No teratogenic effects were seen when benazepril and hydrochlorothiazide were administered to pregnant rats at a dose ratio of 4:5. On a mg/kg basis, the doses used were up to 167 times the maximum recommended human dose. Similarly, no teratogenic effects were seen when benazepril and hydroclorothiazide were administered to pregnant mice at total doses up to 160 mg/kg/day, with benazepril:hydrochlorothiazide ratios of 15:1. When hydrocholorothiazide was orally administered without benazepril to pregnant mice and rats during their respective periods of major organogenesis, at doses up to 3000 and 1000 mg/kg/day respectively, there was no evidence of harm to the fetus. Similarly, no teratogenic effects of benazepril were seen in studies of pregnant rats, mice, and rabbits; on a mg/kg basis, the doses used in those studies were

> 300 times (in rats), 90 times (in mice), and more than 3 times (in rabbits) the maximum recommended human dose.
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> * * *
>
> **Pregnancy**
> ***Pregnancy Categories C (first trimester) and D (second and third trimesters):*** See WARNINGS, Fetal/Neonatal Morbidity and Mortality.[2]

[Novartis Lotensin HCT® Package Insert, Doc. 11-2].

Plaintiff specifically alleges in her Complaint that on June 8, 2006, nearly two and a half years after the Plaintiff stopped taking Lotensin HCT® due to her pregnancy,[3] the New England Journal of Medicine published the results of a study ("Cooper Study") in which investigators found that infants exposed to ACE inhibitors during the first trimester were found to be at a significant increased risk of birth defects, including malformations of the cardiovascular system. [Complaint, Doc. 1-3 at ¶15].

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[2]A Pregnancy Category C warning means that animal studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, or that no animal reproduction studies have been conducted and there are no adequate and well-controlled studies in pregnant women, but that the benefits from the use of the drug in pregnant women may be acceptable despite the risks. 21 C.F.R. §201.57(c)(9)(i)(A)(3). A Pregnancy Category D warning means that there is positive evidence of human fetal risk, but that the potential risk may be outweighed by the benefits of the therapy. 21 C.F.R. §201.57(c)(9)(i)(A)(4).

[3]The Plaintiff resumed taking Lotensin HCT® after the birth of her son. [Complaint, Doc. 1-3 at ¶ 9].

The Cooper Study prompted the FDA to issue a Public Health Advisory, which stated, in pertinent part, as follows:

> While the results of this single study do not establish a causal relationship between exposure to the drugs early in pregnancy and birth defects, they are concerning. ACE inhibitors are already known to have risks to the developing infant when used in the last six months of pregnancy. The prescribing information for all ACE inhibitor drugs has long emphasized that women who become pregnant should be taken off ACE inhibitors as soon as possible to avoid exposure of the fetus in the second and third trimesters, which is known to cause fetal abnormalities, especially related to the kidneys and related structures. The findings from this new study . . . confirm the importance of this recommendation.
>
> * * *
>
> At this time, based on this one observational study, the FDA does not plan to change the pregnancy categories for ACE inhibitors . . . .

[FDA Public Health Advisory, Angiotensin-Converting Enzyme Inhibitor (ACE Inhibitor) Drugs and Pregnancy, dated June 7, 2006, Doc. 11-3].[4]

The Plaintiff filed this present action on July 27, 2006 in the General Court of Justice, Superior Court Division, for Mecklenburg County. [Complaint, Doc. 1-3]. The matter was removed to this Court in August 28,

[4]The Public Health Advisory was issued the day prior to the formal publication of the Cooper Study.

2006. [Notice of Removal, Doc. 1]. In her Complaint, the Plaintiff alleges that "[d]espite knowledge of reported incidents of birth defects associated with first trimester use of ACE Inhibitor blood pressure medicines such as Lotensin HCT ®, and studies revealing birth defects to infants after first trimester use of ACE Inhibitors by the mothers, Defendant promoted and marketed Lotensin HCT ® as safe for use during the first trimester of gestation." [Complaint, Doc. 1-3 at ¶ 12]. She further alleges as follows:

> In its package insert for Lotensin HCT ®, the Defendant warns against the use of Lotensin HCT ® by women during the second and third trimesters due to a link to birth defects, but *failed to give any warning to women of child bearing years or those in their first trimester of pregnancy to avoid using Lotensin HCT ®.* To the contrary, Defendant proactively stated that fetal injury does not appear to be associated with use of Lotensin HCT ® during the first trimester of pregnancy.

[Id. at ¶ 13] (emphasis added). The Plaintiff asserts five different causes of action, including claims of negligence, wantonness, failure to warn, breach of warranty of merchantability, and a claim for "fraud, misrepresentation and suppression." [Id. at ¶¶ 16-46].

In support of its Motion to Dismiss [Doc. 10], the Defendant argued that Plaintiff's claims directly conflict with the pregnancy category classifications and warnings approved and mandated by the FDA for

products containing ACE inhibitors, such as Lotensin HCT®. [Memorandum in Support of Defendant's Motion to Dismiss, Doc. 11 at 2]. The Magistrate Judge agreed, concluding that if the Plaintiff's "state law claims were allowed to proceed, they would clearly conflict with plainly stated purposes and objectives of Congress." [Memorandum and Recommendation, Doc. 26 at 9]. Specifically, the Magistrate Judge reasoned as follows:

> [T]he FDA has concluded that state law claims concerning the labeling of prescription drugs are preempted by federal law. See 71 Fed. Reg. 3922, 3934-36 (Jan. 26, 2006) ("Preemption Preamble"). The Preemption Preamble identifies the FDA's concern over competing state laws as follows:
>
> > If State authorities, including judges and juries applying State law, were permitted to reach conclusions about the safety and effectiveness information disseminated with respect to drugs for which FDA has already made a series of regulatory determinations based on its considerable institutional expertise and comprehensive statutory authority, the federal system for regulation of drugs would be disrupted.
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> 71 Fed. Reg. at 3969.
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> In addition to the FDA's unequivocal statement on this issue, other courts have examined the question of preemption in this field

> and concluded that state law claims based on the premise of a failure to warn in regards to prescription drugs are preempted. See, e.g., Colacicco [v. Apotex, Inc., 432 F.Supp.2d 514, 536-38 (E.D. Pa. 2006)] (noting that "Congress established the elaborate system of legislation for the introduction of new drugs" and that state law claims were not envisioned by Congress); and Ehlis v. Shire Richwood, Inc., 233 F.Supp.2d 1189, 1198 (D.N.D. 2002)(finding that the "FDA dictates the contents of the label . . . and defendants were prohibited from changing it without prior approval from the FDA, except in limited circumstances for a limited period of time"). As the district court persuasively put it in Colacicco, "it is far more desirable that the important issues presented by this case, indeed tragic in its facts, are better addressed by elected officials, legislative and executive, than by . . . judges, a belief which itself has been echoed by the Supreme Court." 432 F.Supp.2d at 536 (citations omitted).

[Memorandum and Recommendation, Doc. 26 at 7-9] (footnotes omitted).

The Plaintiff objects to the Magistrate Judge's Memorandum and Recommendation [Doc. 26], arguing: (1) that the Magistrate Judge incorrectly held that the Preamble is unequivocal evidence that the FDA intended to preempt all state laws affecting prescription drug labeling, including Plaintiff's tort lawsuit; (2) that the Magistrate Judge failed to consider Congressional intent and instead considered only the FDA's intent; (3) that the Magistrate Judge's Memorandum is "against the weight

of the evidence," in that the FDA has not affirmatively considered the warning or the medical and scientific basis for the warning that the Plaintiff alleges to be inadequate and defective; (4) that the Magistrate Judge erred in concluding that the Plaintiff's claims were in actual and direct conflict with federal law; and (5) that the Magistrate Judge failed to distinguish case law specifically holding that the Preamble does not preempt state tort lawsuits. [Plaintiff's Objections to Magistrate Judge's Memorandum and Recommendation on Motion to Dismiss, Doc. 27 at 1-3].

II. STANDARD OF REVIEW

A party may file written objections to the Magistrate Judge's memorandum and recommendation within ten days after being served with a copy of the recommended disposition. 28 U.S.C. § 636(b)(1); Fed. R. Civ. P. 72(b)(2). Such objections must be made "with sufficient specificity so as reasonably to alert the district court of the true ground for the objection." United States v. Midgette, 478 F.3d 616, 622 (4th Cir.), cert. denied, 127 S.Ct. 3032, 168 L.Ed.2d 749 (2007). The Court is not required to review, under a *de novo* or any other standard, the factual or legal conclusions of the magistrate judge to which no objections have been raised. Thomas v. Arn, 474 U.S. 140, 150, 106 S. Ct. 466, 472, 88 L. Ed.

2d 435 (1985). Additionally, the Court need not conduct a *de novo* review where a party makes only "general and conclusory objections that do not direct the court to a specific error in the magistrate's proposed findings and recommendations." Orpiano v. Johnson, 687 F.2d 44, 47 (4th Cir. 1982).

In reviewing a Rule 12(b)(6) motion, "the court should accept as true all well-pleaded allegations and should view the complaint in a light most favorable to the plaintiff." Mylan Labs, Inc. v. Matkari, 7 F.3d 1130, 1134 (4th Cir. 1993), cert. denied, 510 U.S. 1197, 114 S. Ct. 1307, 127 L. Ed. 2d 658 (1994). The plaintiff's "[f]actual allegations must be enough to raise a right to relief above the speculative level." Bell Atlantic Corp. v. Twombly, __ U.S. __, 127 S.Ct. 1955, 1965, 167 L.Ed.2d 929 (2007). "[O]nce a claim has been stated adequately, it may be supported by showing any set of facts of consistent with the allegations in the complaint." Id. at 1969. A complaint will survive a Rule 12(b)(6) motion to dismiss if it sets forth "enough facts to state a claim to relief that is plausible on its face." Id. at 1974.

In considering a motion to dismiss pursuant to Rule 12(b)(6), the Court is confined to the allegations stated in the pleadings. If "matters outside the pleadings are presented to and not excluded by the court, the

motion then must be treated as one for summary judgment under Rule 56." Fed. R. Civ. P. 12(d). While the parties in the present case make reference to matters outside the pleadings, i.e., the Lotension HCT® package insert and the FHA Public Health Advisory, such references do not require the Court to treat Defendant's motion as one for summary judgment. Because the Lotensin HCT® package insert is integral to and explicitly relied on in the Complaint, and the Plaintiff does not challenge its authenticity, the entire insert can be considered in a motion to dismiss without converting the motion to one for summary judgment. See American Chiropractic Ass'n, Inc. v. Trigon Healthcare, Inc., 367 F.3d 212, 234 (4th Cir.) ("When a defendant attaches a document to its motion to dismiss, 'a court may consider it in determining whether to dismiss the complaint [if] it was integral to and explicitly relied on in the complaint and [if] the plaintiff do not challenge its authenticity.'") (quoting Phillips v. LCI Int'l, Inc., 190 F.3d 609, 618 (4th Cir. 1999)), cert. denied, 543 U.S. 979, 125 S.Ct. 479, 160 L.Ed.2d 356 (2004). Further, the Court may take judicial notice of and consider the public records of the FDA, such as the Public Health Advisory, without transforming this motion into a motion for summary judgment. See Pension Benefit Guar. Corp. v. White Consol.

Indus., Inc., 998 F.2d 1192, 1197 (3d Cir. 1993), cert. denied, 510 U.S. 1042, 114 S.Ct. 687, 126 L.Ed.2d 655 (1994); Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514, 526 n.10 (E.D. Pa. 2006).

III. ANALYSIS

A. FDA Regulation of Prescription Drugs

Prior to the enactment of the False Branding or Marking Act of 1902, codified at 21 U.S.C. § 16, et seq., the regulation of the labeling of food and drugs was relegated largely to the States. See In re Vioxx Products Liab. Litig., 501 F.Supp.2d 776, 782 (E.D. La. 2007) (discussing FDA regulatory history). The False Branding or Marking Act was enacted to prohibit the marketing of "any dairy or food products which shall be falsely labeled or branded as to the State or Territory in which they are made, produced, or grown." Id. A few years later, Congress broadened this prohibition to preclude the manufacture and shipment of adulterated or misbranded food and drugs. Pure Food and Drug Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (repealed 1938). See In re Vioxx, 501 F.Supp.2d at 782. In 1938, Congress significantly expanded the scope of its regulation of food and drugs with the enactment of the Federal Food, Drug, and Cosmetic Act ("FDCA"), codified as amended at 21 U.S.C. § 301, et seq.

The FDCA prohibits "[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded." 21 U.S.C. § 331(a).

By enacting the FDCA, Congress granted the Food and Drug Administration (FDA) broad authority to regulate the marketing of prescription drugs in the United States. See 21 U.S.C. §§ 393(b)(1) and 393(b)(2)(B). Among its regulatory duties, the FDA is responsible for reviewing and approving all prescription drugs that are marketed in the United States to ensure "that drugs are safe and effective and that their labeling . . . is truthful and not misleading." Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006).

In order to obtain permission to market a new drug, a manufacturer must first submit a "new drug application" (NDA) for the FDA's review and approval. 21 U.S.C. § 355(a), (b). The NDA must include information about the clinical trials that demonstrate the safety and effectiveness of the product, proposed labeling, and other information. 21 U.S.C. § 355(b), (d). FDA regulations require that the labeling include a warning section which "must describe clinically significant adverse reactions," including reactions

that are potentially fatal, are infrequent but serious, or those which can be prevented or otherwise mitigated through appropriate use of the drug. 21 C.F.R. § 201.57(c)(6)(i).

If the FDA finds that the NDA would be approvable if certain changes were made or certain conditions were met, it will send the applicant an "approvable letter" describing the information that the FDA requires or the conditions that the applicant must meet to obtain approval. 21 C.F.R. § 314.110(a). Before reaching a final decision on the NDA, the FDA will convene an advisory committee to consider the NDA and the FDA's analysis of it. 21 C.F.R. § 14.160. If, after reviewing the application, the FDA finds that the drug is safe and effective for its intended use and that the labeling is not false or misleading, the FDA will send an approval letter to the applicant. 21 U.S.C. § 355(c)(1)(A).

The FDA continues to monitor the safety of drugs after approval. Once a drug has been approved by the FDA, the drug manufacturer is required to maintain records on the drug and report on any additional testing or clinical evidence as directed. Significant adverse drug experiences learned by the manufacturer during the use of the drug must be reported to the FDA. 21 U.S.C. § 355(k)(1); 21 C.F.R. §§ 314.80 and

314.81. The FDA is statutorily authorized to withdraw approval of a drug if scientific data indicates that the drug is not safe or if new information reveals that the labeling of the drug "is false or misleading in any particular." 21 U.S.C. § 355(e).

A drug manufacturer may make certain changes to a drug's label after approval. This may be accomplished by submitting a supplemental NDA, which requires FDA approval before a requested label change can be made, 21 C.F.R. § 314.70(b), or by submitting a "Changes Being Effected" (CBE) supplement, which permits the manufacturer to make the label change without prior FDA approval. 21 C.F.R. § 314.70(c)(6)(iii). CBE supplements can include label changes which (1) add or strengthen a contraindication, warning, precaution or adverse reaction; (2) add or strengthen a statement about drug abuse, dependence, psychological effect or over dosage; (3) add or strengthen instructions about dosage and administration that is intended to increase the safe use of the drug; or (4) delete false, misleading or unsupported indication for the drug's use or claims of effectiveness. 21 C.F.R. § 314.70(c)(6)(iii)(A)-(D). FDA regulations provide that "the labeling must be revised to include a warning about a clinically significant hazard as soon as there is reasonable

evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved." 21 C.F.R. § 201.57(c)(6).

B. General Principles of Preemption

The Supremacy Clause, Article VI, Clause 2 of the United States Constitution "invalidates state laws that 'interfere with, or are contrary to,' federal law." Hillsborough County v. Automated Med. Labs., Inc., 471 U.S. 707, 712, 105 S.Ct. 2371, 2375, 85 L.Ed.2d 714 (1985) (quoting Gibbons v. Ogden, 9 Wheat. 1, 211, 6 L.Ed. 23 (1824)). State laws can be preempted by federal regulations as well as by federal statutes. "Regulations duly promulgated by a federal agency pursuant to a Congressional delegation have the same preemptive effect as a legislative enactment." City of Charleston v. A Fisherman's Best, Inc., 310 F.3d 155, 169 (4th Cir. 2002), cert. denied, 539 U.S. 926, 123 S.Ct. 2573, 156 L.Ed.2d 602 (2003). The imposition of damages is a form of state law that may be subject to preemption. See Geier v. Am. Honda Motor Co., 529 U.S. 861, 881, 120 S.Ct. 1913, 1925, 146 L.Ed.2d 914 (2000).

"Consideration under the Supremacy Clause starts with the basic assumption that Congress did not intend to displace state law." Maryland v. Louisiana, 451 U.S. 725, 746, 101 S.Ct. 2114, 2129, 68 L.Ed.2d 576

(1981). This presumption against preemption "is strongest when Congress legislates 'in a field which the States have traditionally occupied.'" Southern Blasting Services, Inc. v. Wilkes County, 288 F.3d 584, 590 (4th Cir. 2002) (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 485, 116 S.Ct. 2240, 2250, 135 L.Ed.2d 700 (1996)). The Supreme Court has recognized that the protection of the health and safety of citizens has long been the primary responsibility of the States. See Lohr, 518 U.S. at 485, 116 S.Ct. at 2250; Hillsborough County, 471 U.S. at 719, 105 S.Ct. at 2378 ("the regulation of health and safety matters is primarily, and historically, a matter of local concern"). Thus, Courts assume that the States' exercise of police power will not be superseded by federal law absent a "clear and manifest purpose of Congress." Hillsborough County, 471 U.S. at 719, 105 S.Ct. at 2378 (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230, 67 S.Ct. 1146, 1152, 91 L.Ed. 1447 (1947)).

Preemption of state law may occur in one of three ways. "Of course, Congress explicitly may define the extent to which its enactments pre-empt state law." Schneidewind v. ANR Pipeline Co., 485 U.S. 293, 299, 108 S.Ct. 1145, 1150, 99 L.Ed.2d 316 (1988). Absent express Congressional intent, preemption may be implied "where the pervasiveness of the federal

regulation precludes supplementation by the States, where the federal interest in the field is sufficiently dominant, or where 'the object sought to be obtained by the federal law and the character of obligations imposed by it . . . reveal the same purpose." Schneidewind, 485 U.S. at 300, 108 S.Ct. at 1150; see also Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516, 112 S.Ct. 2608, 2617, 120 L.Ed.2d 407 (1992) ("Congress' intent to preempt state law may be implied when 'federal law so thoroughly occupies a legislative field as to make reasonable the inference that Congress left no room for the States to supplement it.") (citations omitted). Finally, even where Congress has not impliedly occupied an entire field of regulation, a state law may be preempted when it actually conflicts with federal law. Conflict preemption occurs where "it is impossible to comply with both state and federal law, or where the state law stands as an obstacle to the accomplishment of the full purposes and objectives of Congress." Schneidewind, 485 U.S. at 300, 108 S.Ct. at 1150-51 (citations omitted).

C. Conflict Preemption

The parties agree that of the three types of preemption, only conflict preemption is at issue in this case. The Plaintiff argues that the Magistrate Judge erred in concluding that conflict preemption applies because no

direct and actual conflict exists between Plaintiff's claims and federal law. The Plaintiff further argues that in concluding that the Plaintiff's claims were preempted due to a conflict with federal law, the Magistrate Judge erred in relying upon the intent of the FDA, as stated in the Preamble, and not the intent of Congress. The Plaintiff also contends that the Magistrate Judge failed to consider a line of cases which have rejected the FDA's position on preemption as stated in the Preamble and have instead concluded that state law claims based upon inadequate labeling or warnings are not preempted by federal regulations. [Plaintiff's Objections to Magistrate Judge's Memorandum and Recommendation on Motion to Dismiss, Doc. 27 at 1-3].

1. FDA's Position on Preemption

On January 24, 2006, the FDA issued a final rule entitled "Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products," 71 Fed. Reg. 3922 (Jan. 24, 2006) ("Final Rule"). In the Preamble to the Final Rule, the FDA states its position regarding the preemption of state law claims based upon allegations of inadequate labeling:

> FDA believes that State laws conflict with and stand as an obstacle to achievement of the full objectives

> and purposes of Federal law when they purport to compel a firm to include in labeling or advertising a statement that FDA has considered and found scientifically unsubstantiated. In such cases, including the statement in labeling or advertising would render the drug misbranded under the act (21 U.S.C. § 352(a) and (f)).

71 Fed. Reg. at 3935. The FDA further states in the Preamble that state law actions based on claims of inadequate label warnings create the risk that a manufacturer will be held liable for failing to include a warning that was not approved by the FDA or was specifically rejected by the FDA due to a lack of scientific evidence:

> State law actions also threaten FDA's statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs. State actions are not characterized by centralized expert evaluation of drug regulatory issues. Instead, they encourage, and in fact require, lay judges and juries to second-guess the assessment of benefits versus risks of a specific drug to the general public -- the central role of FDA -- sometimes on behalf of a single individual or a group of individuals. That individualized reevaluation of the benefits and risks of a product can result in relief -- including the threat of significant damage awards or penalties -- that creates pressure on manufacturers to attempt to add warnings that FDA has neither approved nor found to be scientifically required. This could encourage manufacturers to propose "defensive labeling" to avoid State liability, which, if implemented, could result in scientifically

> unsubstantiated warnings and under utilization of beneficial treatments.

71 Fed. Reg. at 3935.

In the FDA's view, allowing state tort claims for inadequate warnings creates the risk that manufacturers will alter their warnings to exaggerate risks so as to avoid state tort liability, thus "discourag[ing] appropriate use of a beneficial drug." 71 Fed. Reg. at 3935. The FDA states that such "overwarning" could result in a negative impact on patient safety and public health by causing "meaningful risk information to lose its significance." Id.

Several courts which considered the issue of conflict preemption have concluded that the FDA's position on preemption as stated in the Preamble is entitled to considerable deference. See, e.g., Colacicco v. Apotex, Inc., 432 F.Supp.2d 514, 529 (E.D. Pa. 2006); Dobbs v. Wyeth Pharm., __ F.Supp.2d __, No. CIV-04-1762-D, 2008 WL 169021, at *12 (W.D. Okla. Jan. 17, 2008); In re Bextra and Celebrex Marketing Sales Practices and Product Liab. Litig., No. M:05-1699 CRB, 2006 WL 2374742, at *6 (N.D. Cal. Aug. 16, 2006); Abramowitz v. Cephalon, Inc., 2006 WL 560639, at *3 (N.J. Super. Ct. L. Div. Mar. 3, 2006). Other courts, however, have concluded that the Preamble is not entitled to considerable deference and that, despite the express statements of the FDA to the

contrary, federal regulations of prescription drug labeling continue to set only a "minimum standard" which may be supplemented by state law. See, e.g., In re Vioxx Products Liability Litigation, 501 F.Supp.2d 776, 788 (E.D. La. 2007); In re Zyprexa Products Liab. Litig., 489 F.Supp.2d 230, 273 (E.D.N.Y. 2007); Weiss v. Fujisawa Pharm. Co., 464 F.Supp.2d 666, 674 (E.D. Ky. 2006); Perry v. Novartis Pharma. Corp., 456 F.Supp.2d 678, 684 (E.D. Pa. 2006); Jackson v. Pfizer, Inc., 432 F.Supp.2d 964, 968 (D. Neb. 2006); see also McNellis ex rel. DeAngelis v. Pfizer, Inc., NO. Civ. 05-1286(JBS), 2006 WL 2819046, at *5 (D.N.J. Sep. 29, 2006) (while giving deference to the FDA's interpretation of its own regulations, finding that such interpretation is not dispositive of the preemption issue).

In the present case, the Defendant argues that the FDA's position on preemption as stated in the Preamble is entitled to considerable deference by this Court in determining whether conflict preemption applies. [Defendant's Memorandum in Support of Motion to Dismiss, Doc. 11 at 11]. The Plaintiff argues, on the other hand, that it is the intent of Congress which must be examined in determining whether preemption applies, not the intent of the FDA. [Plaintiff's Objections to Magistrate Judge's Memorandum and Recommendation, Doc. 27 at 10]. The Plaintiff argues

that in amending the FDCA in 1962, Congress expressly stated its intention that the FDCA shall not be construed as preempting any state law "unless there is a direct and positive conflict" between the two, citing the Drug Amendments of 1962, Section 202, 52 Stat. 1040, 21 U.S.C. § 301. [Plaintiff's Objections to Magistrate Judge's Memorandum and Recommendation, Doc. 27 at 10]. Further, the Plaintiff argues, the 1997 amendment to the FDCA does not contain any statement regarding the preemptive effective of the FDCA. Absent an express preemption provision, Plaintiff argues, it should be presumed that Congress did not intend to preempt state law actions. [Id. at 11-12].

The Plaintiff is correct that the issue of preemption usually requires an analysis of the intent of Congress, and that absent an express statement of preemption, it is usually presumed that Congress did "not intend to supplant state law." New York State Conf. v. Travelers Ins. Co., 514 U.S. 645, 654, 115 S.Ct. 1671, 1676, 131 L.Ed.2d 695 (1995). However, conflict preemption may occur even when Congress did not intend to preempt state law in a given area. A Fisherman's Best, 310 F.3d at 169. Conflict preemption analysis therefore "turns on the identification of 'actual conflict,' and not on an express statement of pre-emptive intent."

Geier, 529 U.S. at 884, 120 S.Ct. at 1927. Thus, consideration of the stated intent of Congress or the FDA (as expressed in the Preamble) is not necessarily determinative of whether Plaintiff's failure to warn or inadequate labeling claims conflict with federal regulations. See O'Neal v. Smithkline Beecham Corp., No. CIV S-06-1063 FCD/DAD, 2008 WL 275782, at *8 (E.D. Cal. Jan. 30, 2008). Rather, the dispositive issue before the Court is: do the Plaintiff's state law claims for inadequate labeling and/or failure to warn conflict with the requirements of federal law such that a finding of preemption is warranted in this case?

The District Court for the Eastern District of Pennsylvania addressed a similar issue in Sykes v. Glaxo-Smithkline, 484 F.Supp.2d 289 (E.D. Pa. 2007). In that case, the plaintiff alleged that the defendant Bayer failed to warn consumers adequately about the toxic levels of mercury in the thimerosal preservative used in HypRho-D, an immune globulin administered to the plaintiff while she was pregnant with her son. Id. at 292. The Court rejected the plaintiff's claim, finding that such a warning would directly conflict with the warnings expressly considered and approved by the FDA:

> [T]he FDA package insert disclosed the presence of mercury in thimerosal and warned that HypRho-D

> "should be given with caution . . . to patients who are known to have had an allergic response to thimerosal" and it is "not known whether [HypRho-D] can cause fetal harm when administered to a pregnant women [sic] [and] should be given to a pregnant woman only if clearly needed." If Bayer had inserted a warning about the alleged toxicity of thimerosal, it would have been directly contrary to the FDA's decision concerning the nontoxic characteristic of that preservative. See 21 C.F.R. § 610.15; 21 U.S.C. § 352. And if Bayer added the plaintiffs' additional warnings about the alleged risks of injury resulting from thimerosal, the label content would not have been substantiated by "reasonable evidence of an association of a serious hazard with a drug."

Sykes, 484 F.Supp.2d at 311.

Similarly, in the present case, the Plaintiff alleges that the Defendant failed to provide adequate warnings regarding the association between birth defects and fetal injury with taking Lotensin HCT ® during the first trimester of pregnancy. Specifically, the Plaintiff argues that the Defendant should be held liable for failing to warn the Plaintiff and the general public that (1) there are "dangerous" and "significant" risks of birth defects and injury to a fetus from the use of Lotensin HCT ® during the first trimester of gestation"; (2) Lotensin HCT ® should not be used by pregnant patients during the first trimester of gestation or during the time during which women of child bearing years attempt to become pregnant; and (3)

Lotensin HCT ® had not been adequately and thoroughly studied or tested for safety as a blood pressure medication for women during the first trimester of pregnancy or for the time during which women of child bearing years attempt to become pregnant. [Complaint, Doc. 1-3 at ¶ 32]. The text of the warning label as approved by the FDA indicates that the FDA affirmatively considered the medical and scientific proof available at the time and concluded that the risks of birth defects and fetal injury do not appear to result from the use of the drug during the first trimester:

> These adverse effects do not appear to have resulted from intrauterine ACE-inhibitor exposure that has been limited to the first trimester. Mothers whose embryos and fetuses are exposed to ACE inhibitors only during the first trimester should be so informed. Nonetheless, when patients become pregnant, physicians should make every effort to discontinue the use of benazepril as soon as possible.

[Novartis Lotensin HCT® Package Insert, Doc. 11-2].

To hold the Defendant liable for failing to provide an additional warning to the effect that use of Lotensin HCT ® during the first trimester poses risks of birth defect and fetal injury when the FDA has already determined that such risks do not appear to result from use of the drug in the first trimester would create a direct conflict between the requirements

of federal law and the requirements of state law and would place the Defendant in an impossible situation whereby the Defendant could not comply with federal law and state law at the same time.

Furthermore, the Plaintiff has not alleged that, at the time of her pregnancy, the Defendant possessed any studies revealing birth defects associated with the first trimester use of Lotensin HCT® in particular or ACE inhibitors in general.[5] Nor has the Plaintiff alleged that the Defendant had any "reasonable evidence" of such a causal association at the time of her pregnancy which would have required the revision of the labeling pursuant to 21 C.F.R. § 201.57(c)(6). In fact, Plaintiff's own allegations suggest the contrary. Plaintiff alleges that in 2006, the Cooper Study reported a possible link between first trimester exposure to ACE inhibitors and increased risk of birth defects. The FDA's June 2006 Public Health Advisory indicates that the evidence published in the Cooper Study was the first of its kind, as the FDA noted that the results of "this one

[5]Indeed, the Plaintiff admits in her brief that she "does not anticipate that there will be any evidence that the FDA requested or held a single advisory committee meeting to discuss ACE inhibitors and risks associated with their use in the first trimester of pregnancy." [Plaintiff's Objections to Magistrate Judge's Memorandum and Recommendation on Motion to Dismiss, Doc. 27 at 14]. Nor does the Plaintiff believe that there will "be any evidence that the FDA considered any of the proposed warnings advocated by the Plaintiff's claims." [Id.].

observational study" did not merit any change to the pregnancy categories or warnings for ACE inhibitors. [FDA Public Health Advisory, Angiotensin-Converting Enzyme Inhibitor (ACE Inhibitor) Drugs and Pregnancy, Doc. 11-3]. Plaintiff acknowledges in her Complaint that she discontinued use of Lotensin some two and a half years before the Cooper Study was published. Given the lack of scientific evidence of an association of birth defects and the use of ACE inhibitors during the first trimester, during the relevant period, if the Defendant had added the additional warnings advocated by the Plaintiff, the label content would not have been substantiated by "reasonable evidence of a causal association" between the serious hazard claimed and the drug. See 21 C.F.R. § 201.57(c)(6); see also O'Neal, 2008 WL 275782, at *8 ("Had GSK included the warning plaintiffs urge, contrary to the FDA's approvals and absent reasonable evidence at the time, it would have misbranded the drug in violation of the FDCA. Thus, plaintiffs' claims are preempted.").

For the foregoing reasons, the Court concludes that the Magistrate Judge correctly concluded, based on Plaintiff's allegations, that a direct and positive conflict exists between federal law and Plaintiff's state law claims for inadequate labeling and/or failure to warn. The Plaintiff's

Objections are therefore overruled with respect to the Magistrate Judge's Recommendation that the Plaintiff's failure to warn and inadequate labeling claims are preempted.

D. Plaintiff's Remaining Claims

Upon reviewing each of the claims set forth in the Plaintiff's Complaint [Doc. 1-3], the Magistrate Judge found that "[t]he underlying basis for each claim is that the Defendant failed to properly label and warn the Plaintiff of the potential for harm," and thus concluded that all of the Plaintiff's claims are subject to preemption and should be dismissed. [Memorandum and Recommendation, Doc. 26 at 9]. The Court agrees with the Magistrate Judge that many of the Plaintiff's claims are based upon an allegation that the Defendant failed to label the drug properly and warn the Plaintiff of the potential for harm, including her claims related to the Defendant's advertising, marketing, labeling, packaging and promotion of Lotensin HCT ®. A careful review of the Plaintiff's Complaint, however, reveals that the Plaintiff asserts claims that go beyond merely alleging a failure to warn or inadequate labeling. Accordingly, the Court finds that the Magistrate Judge's conclusion that *all* of the Plaintiff's claims are prempted by the FDA's regulation of drug labeling was in error. As such, the Court

will address the substantive arguments raised in the Defendant's Motion to Dismiss [Doc. 10] as to each of these remaining claims.

1. Count One: Negligence

The Defendant moves for dismissal of the Plaintiff's negligence claim, arguing that all of the Plaintiff's factual allegations focus exclusively on Defendant's alleged failure to provide adequate warnings regarding the use of Lotensin HCT® during the first trimester of pregnancy, and that the Plaintiff makes no specific factual allegations regarding the alleged negligent manufacturing, design, testing, research, development, distribution, and sale of Lotensin HCT®. The Defendant further argues that the Complaint fails to provide actual notice of the basis for the Plaintiff's negligence claim with respect to these issues. [Defendant's Memorandum in Support of Motion to Dismiss, Doc. 11 at 16].

Rule 8 of the Federal Rules of Civil Procedure requires that a Complaint set forth "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Thus, "detailed factual averments are no longer necessary to avoid dismissal of a claim" pursuant to Rule 12(b)(6). Bolding v. Holshouser, 575 F.2d 461, 464 (4th Cir. 1978). Rather, the determinative issue is whether the plaintiff's factual

allegations "raise a right to relief above the speculative level." Twombly, 127 S.Ct. at 1965. "The pleading must contain something more than a statement of facts that merely creates a suspicion of a legally cognizable right of action." Id. (quoting 5 Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 1216 (3d ed. 2004)) (ellipses in original omitted).

In order to establish a claim for negligence under North Carolina law, the Plaintiff must establish the following elements: "duty, breach of duty, proximate cause, and damages." Camalier v. Jeffries, 340 N.C. 699, 706, 460 S.E.2d 133, 136 (1995). In order to survive a Rule 12(b)(6) motion, "a complaint asserting a negligence claim must disclose 'that each of the elements is present . . . .'" Iodice v. United States, 289 F.3d 270, 281 (4th Cir. 2002) (quoting 5 Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 1249 (2d ed. 1990 & Supp. 2001)).

In the present case, the Plaintiff alleges that the "Defendant negligently manufactured, designed, tested, researched and developed, labeled, packaged, distributed, promoted, marketed, advertised and sold Lotensin HCT ®, in the State of North Carolina [Complaint, Doc. 1-3 at ¶ 17]; that the "Defendant had a duty to exercise reasonable care in the

design, manufacture, research and development, testing, processing, advertising, marketing, labeling, packaging, distribution, promotion and sale of its medications" [Id. at ¶ 18]; and that this Defendant breached that duty by, among other things, failing to use reasonable care to study, investigate and test Lotensin HCT® and failing to use reasonable care to design and manufacture a blood pressure medication safe for its intended use, [Id. at ¶ 19]. Plaintiff particularly alleges with regard to such failure to study that it had been "properly performed, [it] would have shown that Lotensin HCT ® had [sic] serious side effects on fetuses during the first trimester, including but not limited to infant birth defects such as[] heart malformations, ventricular septal defect, spina bifida, microcephaly and other malformations." [Id. at ¶ 19.a.]. Finally, the Plaintiff asserts that "[a]s a direct and proximate result of the negligent actions and inactions of the Defendant ..., Zachary Clifton Horne sustained birth defect injuries from which he died." [Id. at ¶ 21]. While these allegations leave much to be desired to demonstrate to the Court that they reflect more than mere speculation that the Plaintiff hopes she has a claim, see Twombly, 127 S.Ct. at 1965, these allegations are sufficiently factual to state a cognizable claim for negligence and to give the Defendant "fair notice of

what [the Plaintiff's] claim is and the grounds upon which it rests." See Hatfill v. New York Times Co., 416 F.3d 320, 337 (4th Cir. 2005) (quoting Swierkiewicz v. Sorema N.A., 534 U.S. 506, 512, 122 S.Ct. 992, 998, 152 L.Ed.2d 1 (2002)), cert. denied, 547 U.S. 1040, 126 S.Ct. 1619, 164 L.Ed.2d 333 (2006). The Court has already determined that the Plaintiff's claims based upon inadequate labeling or failure to warn are preempted by federal law. Accordingly, the Defendant's Motion to Dismiss [Doc. 10] is granted with respect to the Plaintiff's claims for negligent labeling, packaging, promotion, marketing, and advertising. The Defendant's Motion to Dismiss [Doc. 10] is denied with respect to the Plaintiff's negligence claim related to the design, manufacture, research and development, testing, processing, distribution, and sale of Lotensin HCT®.

2. Counts Two and Five

The Defendant also seeks dismissal of Count Two of the Complaint, in which the Plaintiff alleges that the Defendant was reckless and wanton in its actions; that the "Defendant knew that Lotensin HCT ® had unreasonably dangerous risks and caused serious side effects to infants of which Plaintiff would not be aware"; and that the "Defendant nevertheless advertised, marketed, sold and distributed the medicine." [Complaint, Doc.

1-3 at ¶ 26]. Further, the Defendant seeks the dismissal of the Plaintiff's fifth claim, which is characterized as one for "fraud, misrepresentation and suppression." [Complaint, Doc. 1-3 at 7]. In this Count, the Plaintiff alleges that the "Defendant fraudulently, intentionally and/or negligently misrepresented to Plaintiff, Plaintiff's physician, the FDA, and [the] general public, the safety of Lotensin HCT ® and/or fraudulently, intentionally and/or negligently concealed material including adverse information regarding the safety of Lotensin HCT ®." [Id. at ¶ 40]. The Plaintiff alleges that the Defendant made the following misrepresentations:

a. Lotensin HCT ®, when used as recommended, was safe for fetuses/babies while regulating blood pressure of the mother during the first trimester of gestation;

b. Lotensin HCT ® had been sufficiently studied and tested and was safe for fetuses/babies while used as a blood pressure regulator for the mother during the first trimester of gestation;

c. Lotensin HCT ® and ACE Inhibitors in general had been fully and adequately tested and studied for use by pregnant women during the first trimester of gestation;

d. Lotensin HCT ® had no serious side adverse effects on a fetus/baby when used by the mother during the first trimester of her pregnancy; [and]

e. Lotensin HCT ® was safe for a fetus/baby when used by the mother during the first trimester of her pregnancy.

[Id. at ¶ 41].

To the extent that the Plaintiff's claims of wantonness and fraud allege that the Defendant made material misrepresentations to her and her physician through inadequate warnings, these claims are impliedly preempted by federal law, for the reasons discussed supra. To the extent that the Plaintiff claims that the Defendant withheld medical evidence from the FDA or otherwise committed fraud on the FDA, such claims are preempted under the Supreme Court's decision in Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341, 348, 121 S.Ct. 1012, 1017, 148 L.Ed.2d 854 (2001) ("state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law"). Accordingly, the Plaintiff's claims for wantonness and for "fraud, misrepresentation and suppression" also are dismissed.

3. Count Four: Breach of Warranty of Merchantability

The Plaintiff's fourth claim is one for breach of warranty of merchantability. Specifically, the Plaintiff alleges that "Lotensin HCT ® was not of merchantable quality and was not safe or fit for its intended use

because it was unreasonably dangerous and unfit for the ordinary purposes for which it is used, in that Lotensin HCT ® caused serious injuries and damages to the fetuses during the first trimester of gestation." [Complaint, Doc. 1-3 at ¶ 37].

The Defendant argues that this claim should be dismissed because North Carolina law requires an injured buyer to give notice to the seller of the breach of the warranty in order to recover. The Plaintiff counters, on the other hand, that she is not required to plead notice to the seller in order to state a claim for breach of an implied warranty of merchantability.

It is well-established under North Carolina law that a plaintiff may recover for a breach of implied warranty of merchantability without any proof of negligence if the plaintiff can establish the following elements: "(1) a merchant sold goods, (2) the goods were not 'merchantable' at the time of sale, (3) the plaintiff (or his property) was injured by such goods, (4) the defect or other condition amounting to a breach of the implied warranty of merchantability proximately caused the injury, and (5) *the plaintiff so injured gave timely notice to the seller*." Reid v. Eckerds Drugs, Inc., 40 N.C. App. 476, 480, 253 S.E.2d 344, 347, review denied, 297 N.C. 612, 257 S.E.2d 219 (1979) (emphasis added); see also N.C. Gen. Stat. § 25-2-

607(3)(a). "[S]easonable notification is a condition precedent to the plaintiff-buyer's recovery." Maybank v. S.S. Kresge Co., 302 N.C. 129, 133, 273 S.E.2d 681, 683 (1981). "Thus, the burden of pleading and proving that seasonable notification has been given is on the buyer." Id.

However, "[w]hen the plaintiff is a lay consumer and notification is given to the defendant by the filing of an action within the period of the statute of limitations, and when the applicable policies behind the notice requirement have been fulfilled, . . . the plaintiff is entitled to go to the jury on the issue of seasonable notice." Maybank, 302 N.C. at 136, 273 S.E.2d at 685. The North Carolina Court of Appeals has described the policies underlying the notice requirement as follows:

> The policies behind the notice provision are (1) to enable the seller to make efforts to cure the breach by making adjustments or replacements in order to minimize the buyer's damages and the seller's liability; (2) to afford the seller a reasonable opportunity to learn the facts so that he may adequately prepare for negotiation and defend himself in a suit; and (3) to provide a seller with a terminal point in time for liability. Equally important as the above policies is the proposition that a reasonable time for notification from a retail consumer is to be judged by different standards so that in his case it will be extended, for the rule of requiring notification is designed to defeat commercial bad faith, not to deprive a good faith consumer of his remedy.

Bryant v. Adams, 116 N.C. App. 448, 471, 448 S.E.2d 832, 844 (1994) (quoting Maybanks, 302 N.C. at 134-35, 273 S.E.2d at 684-85) (internal quotation marks omitted), review denied, 339 N.C. 736, 454 S.E.2d 647 (1995). The issue of seasonable notice "becomes a question of law only when the facts are undisputed and only one inference can be drawn as to the reasonableness of the notice." Maybank, 302 N.C. at 134, 273 S.E.2d at 684, n.1.

In the present case, the Defendant does not dispute that the Plaintiff's Complaint was filed within the applicable statute of limitations period. [See generally Defendant's Answer, Doc. 9; Defendant's Memorandum in Support of Motion to Dismiss, Doc. 11]. Accordingly, whether the Plaintiff has provided seasonable notice to the Defendant is a factual issue which precludes dismissal of the Plaintiff's breach of warranty claim at this stage.

For these reasons, the Defendant's Motion to Dismiss [Doc. 10] will be denied with respect to the Plaintiff's claim for breach of warranty of merchantability.

V. CONCLUSION

For the reasons stated herein, **IT IS, THEREFORE, ORDERED** that the Plaintiff's Objections [Doc. 27] to the Magistrate Judge's Memorandum and Recommendation [Doc. 26] are **OVERRULED IN PART**, and the Magistrate Judge's Recommendation [Doc. 26] is **ADOPTED IN PART** to the extent that the Magistrate Judge has recommended the dismissal of the Plaintiff's claims premised on a failure to warn or inadequate labeling claims on the grounds of conflict preemption. However, to the extent that the Magistrate Judge recommended dismissal of the Plaintiff's claims which are not premised on a failure to warn or inadequate labeling, the Magistrate Judge's Recommendation [Doc. 26] is **REJECTED IN PART**.

IT IS FURTHER ORDERED that the Defendant's Motion to Dismiss [Doc. 10] is **GRANTED IN PART** with respect to the Plaintiff's claims of negligent labeling, packaging, promotion, marketing, and advertising; her claim of failure to warn; her claim for wantonness; and her claim of fraud, misrepresentation and suppression. The Motion to Dismiss [Doc. 10] is **DENIED IN PART** with respect to the Plaintiff's negligence claim related to the design, manufacture, research and development, testing, processing,

distribution, and sale of Lotensin HCT® and her claim of breach of implied warranty of merchantability.

IT IS SO ORDERED.

Signed: March 25, 2008